SEP 2 8 2004

K041905

Section 3
HemosIL Calibration plasma - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

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Summary Prepared:

July 14, 2004

Name of the Device(s):

HemosIL Calibration plasma

Classification Name(s):

862.1150	Calibrator	Class II
JIX	Calibrator, Multi-Analyte Mixture	

Identification of Predicate Device(s):

K905203	HemosIL Assayed Reference Plasma-Normal (for ELECTRA Series Analyzers)
K002400	Assess Calibration Plasma (for ACL Family of Analyzers) NOTE: FDA cleared as part of the individual ACL Coagulation Analyzers 510(k) submissions; for example, the ACL Advance (K002400).

Description of the Device/Intended Use(s):

HemosIL Calibration plasma is intended for the calibration of coagulation assays on IL and ELECTRA Coagulation Systems. The calibration plasma is prepared using citrated plasma plasmapheresed from healthy donors to maintain the characteristics of a normal plasma pool.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL Calibration plasma is substantially equivalent in performance, intended use and safety and effectiveness to the predicate devices: Assess Calibration Plasma on the ACL Family of Coagulation Analyzers and HemosIL Assayed Reference Plasma-Normal on the ELECTRA Series of Coagulation Analyzers.

Section 3 (Cont.)
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Summary of Performance Data:

Precision testing was performed as part of the value assignment process by running HemosIL Calibration plasma in replicates of eight on four ACL 9000 coagulation analyzers (n=32) with the IL reagents listed below:

Analyte	Reagent	Mean	Within Run %CV
APTT (Seconds)	HemosIL APTT-SP	30.5	1.15
Antithrombin (%)	HemosIL Liquid Antithrombin	104	2.04
Factor V (%)	HemosIL FV Deficient Plasma	117	2.09
Factor VIII (%)	HemosIL FVIII Deficient Plasma	83.2	4.28
Fibrinogen – Clauss (mg/dL)	HemosIL Fibrinogen-C	295	2.30
Fibrinogen - PT-Based (mg/dL)	HemosIL PT-Fib Recombinant	288	5.12
Plasmin Inhibitor (%)	HemosIL Plasmin Inhibitor	97.7	2.02
Plasminogen (%)	HemosIL Plasminogen	84.6	1.59
Protein C (%)	HemosIL ProClot	96.8	4.73
Protein S (%)	HemosIL Protein S	70.9	3.39
PT (Seconds)	HemosIL PT-Fib Recombinant	11.0	1.45
Thrombin Time (Seconds)	HemosIL Thrombin Time (2 mL)	7.59	1.84
	HemosIL Thrombin Time (5 mL)	16.9	2.13
	HemosIL Thrombin Time (8 mL)	24.5	1.27
von Willebrand Factor (%)	HemosIL VWF Antigen	104	1.13

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 8 2004

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: k041905
Trade/Device Name: HemosIL Calibration Plasma
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator, Multi-Analyte Mixture
Regulatory Class: II
Product Code: JIX
Dated: September 17, 2004
Received: September 20, 2004

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K041905

Device Names: HemosIL Calibration plasma

Indications for Use:

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Prescription Use √ (Part 21 CFR 801 Subpart D) **OR** Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041905